

the amount of calcium, phosphorus, iron, and vitamin D required daily by the average person; that the article would bring the body of an underweight person up to normal; that when a reducing diet was used, the article would supply the calcium, phosphorus, iron, and vitamin D, and the necessary additional quantities of the vitamins A, B₁, and G, which the body requires because of the reduction in calories which results from the reducing diet; that when a reducing diet was used, the article when administered in accordance with the Cal-Par Reducing Plan for Eating, would prevent nervousness, tiredness, sleeplessness, and lack of pep and vigor by supplying the body's daily requirements of calcium, phosphorus, iron, and vitamin D; that the use of the article in the absence of glandular or organic complications, would take off surplus fat; that two heaping teaspoonfuls taken daily would supply the average person's daily requirements of phosphorus; that the article was a necessary part of practically every reducing diet; that it would prevent the undermining of health of persons following a reducing diet; that it would enable persons to reduce easily with no undue hardship; that it would help to build sturdy bones and strong teeth; that if used daily, it would supply the amounts of calcium, phosphorus, iron, and vitamin D to bring the body of underweight persons up to normal; that the use of the article in accordance with a specified 7-day reducing plan, would cause the loss of at least 8 pounds per week; that when used in accordance with a specified special reducing plan, the article would cause the body to lose as much as 18 pounds in 12 days; that the article would supply mineral and vitamin deficiencies to the system; that it would supply necessary minerals and vitamins to the system and thereby prevent heart trouble, nervous disorders, kidney ailments, liver ailments, digestive upsets, eye afflictions, and many other ailments which may be a direct result of a lack of certain vitamins and minerals; that it would prevent ailments of the teeth and bones and decay of the teeth by supplying calcium; that it would help in the building of strong teeth and firm bones, in aiding the blood to keep its proper balance between acidity and alkalinity, and in nourishing the nerves and brain; that it would be efficacious in the cure, mitigation, treatment, or prevention of anemic, rundown conditions; that it would be of great advantage to build up resistance to disease; that the use of the article by women during pregnancy would cause the child to be born well-formed and in good health; and that the use of the article would be efficacious in the cure, mitigation, treatment, or prevention of sinus trouble, rheumatism, and arthritis. The article would not fulfill the promises of benefit stated and implied.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 8, 1948. Pleas of guilty having been entered, the court imposed a fine of \$1,000 against the defendants jointly.

2518. Adulteration of isotonic solution of sodium chloride. U. S. v. 22 Cartons
* * *. (F. D. C. No. 25353. Sample No. 1043-K.)

LIBEL FILED: August 10, 1948, Southern District of Florida.

ALLEGED SHIPMENT: On or about January 28, 1948, from Cleveland, Ohio.

PRODUCT: 22 cartons, each containing 6 1,000-cc. flasks, of *isotonic solution of sodium chloride*. The product was contained in hermetically sealed flasks and was intended for intravenous injection.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard, since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 12, 1948. Default decree of forfeiture and destruction.

2519. Adulteration of isotonic solution of three chlorides and isotonic solution of sodium chloride. U. S. v. 54 Flasks, etc. (F. D. C. No. 25344. Sample Nos. 10603-K, 10608-K.)

LIBEL FILED: August 5, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about June 21 and 30, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 54 500-cc. flasks of *isotonic solution of three chlorides* and 12 1,000-cc. flasks of *isotonic solution of sodium chloride* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Sterile Ringer's Solution for Parenteral Use" and "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standard, since they were not substantially free of any turbidity and undissolved material, as required by the Pharmacopoeia, but were contaminated with undissolved material.

DISPOSITION: November 8, 1948. Default decree of condemnation. The products were ordered delivered to the Food and Drug Administration, for official purposes.

2520. Adulteration of solution of sodium chloride. U. S. v. 6 Cases * * *. (F. D. C. No. 25345. Sample No. 9385-K.)

LIBEL FILED: August 6, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about April 27, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 6 cases, each containing 12 flasks, of solution of *sodium chloride* at New York, N. Y. The product was intended for intravenous injection, as evidenced by the statement on the flask label "For the purpose of filling and rinsing the tubing this unit contains 50 cc. in excess of the declared volume."

LABEL, IN PART: "Sodium Chloride 5% in Distilled Water 500 cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it contained undissolved material, whereas an article which is represented for intravenous use should be substantially free of any undissolved material.

DISPOSITION: August 27, 1948. Default decree of condemnation and destruction.

2521. Adulteration and misbranding of A-C-D anticoagulant acid citrate dextrose. U. S. v. 18 Flasks * * *. (F. D. C. No. 25346. Sample No. 10602-K.)

LIBEL FILED: August 5, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about June 18, 1947, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 18 55-cc. flasks of *A-C-D anticoagulant acid citrate dextrose* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Anticoagulant Acid Citrate Dextrose," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality fell below the official standard since it was pyrogenic and contaminated with undissolved material.

Misbranding, Section 502 (a), the label statement "This product is * * * non-pyrogenic" was false and misleading as applied to this article, which contained pyrogen.

DISPOSITION: November 8, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for official purposes.

2522. Adulteration of ampuls of sodium iodide. U. S. v. 11,940 * * * Ampuls etc. (F. D. C. No. 25085. Sample Nos. 10575-K to 10578-K, incl.)

LIBEL FILED: July 13, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 21, 1948, by the Veterans Administration Supply Depot, from Broadview, Ill. This was a return shipment.

PRODUCT: 11,940 20-cc. ampuls and 33,075 10-cc. *ampuls of sodium iodide* at Long Island City, N. Y.

LABEL, IN PART: "20 cc. + Ampule Sodium Iodide 10% W/V Intravenous," or "10 cc. Ampul Sodium Iodide 2 grams for Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.